DETAILED ACTION

Status of the Claims

1. The Claims 1-6, 9-19, 22-28 are pending. Claims 3-4, 11-13, 15-16, 23-24 are withdrawn.

Response to Arguments

2. Applicant's arguments filed on 9/6/2011, with respect to the 35 USC, 112, second paragraph rejection of Claims 9 and 22, have been fully considered and are persuasive. The respect to the 35 USC, 112, second paragraph rejection of Claims 9 and 22 has been withdrawn.

The Examiner notes the particles "comprise" sub-micron particles and therefore at least two particles must be sub-micron, though not all particles must be sub-micron in size.

3. Applicants arguments filed on 9/6/2011 have been fully considered, but they are not persuasive as noted below. The following responses are with respect to the Applicant's arguments regarding the prior art rejections.

4. The Applicant cites a passage in the specification (p. 9, line 28 to p. 10, line 3), which discloses that the goal of the invention is to generate a large amount of bone from mesenchymal stem cells. The Examiner notes that the cited passage is silent to any

distinction between demineralized and pulverized "living" bone, which the arguments that follow focus on.

5. The Applicant then requests the Examiner cite passages to support the previous rejection stating demineralized and pulverized bone are alternatives as disclosed by the Applicant.

The Specification discloses in the background that demineralized bone produces the desired activity of the applicant's invention (to promote bone formation) (Specification, p. 2, lines 4-8). As the Applicant provides no distinction between demineralized bone and pulverized "living" bone, and as both types of bone provide the same result, they are alternatives.

6. The Applicant then discusses the differences between the processes of demineralization and pulverization of bone and states the resulting products are required to be "identical in all material respects". As seen below (last paragraph of this section) by Jefferies (who pulverizes demineralized bone) demineralization and pulverization are not mutually exclusive processes and can be used together to form the claimed structural limitations.

The Examiner notes the Applicant asserts that for the Boyce rejection to be maintained then the product must be inherently taught by Boyce. The Examiner notes the rejection used was not an anticipation reference, but rather an obviousness rejection, noting that all components are not inherent to Boyce alone, but rather obvious over the secondary reference. Therefore, in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references

individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

The Examiner further notes, the disclosure fails to provide support for the criticality argued by the Applicant distinguishing demineralized from pulverized "living" bone. Further, the Specification does not provide any definition for the concept of "living" bone or distinguish pulverized "living" bone from demineralized bone. The Examiner notes there is only a single reference to demineralized bone (Specification, p. 2, lines 4-8).

Further, the Examiner notes that if the claimed structure of the demineralized bone used in the references is structurally the same then it meets the claim limitations. The structural limitations claimed are with respect to the particle size.

Boyce establishes the size of the particles to be sub-micron via reference (column 1, line 52; US Pat 4,349,370 to Jefferies; see column 2, lines 3-9 of Jefferies for demineralized bone powder in the sub-micron range (75 millimicrons to 450 millimicrons or 75 nm to 450 nm) or see claim 3 of Jefferies). Jefferies teaches specifically pulverized (Jefferies, column 3, line 49), demineralized bone powder in the sub-micron range (e.g. Jefferies, claim 3) used in a matrix "complex" of collagen for bone implants/grafts. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Boyce to use sub-micron demineralized bone particles.

7. With respect to the Applicant's arguments regarding the Smith reference, in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

The Applicant notes Smith does not anticipate the product. The Examiner agrees, and notes a 35 USC 103, obvious type rejection was used in combination with Boyce and Chou. The Claim limitations are met as discussed in response to the Boyce arguments (above).

8. The Applicant's additional arguments refer back to those discussed above. The Examiner notes the Applicant discusses the particle size in the Application versus the Chou reference; however, the Applicant does not argue that concept and rather returns to arguments discussed above.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 1, 9-10, 14, 17, 22, 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyce, et al (Boyce) (US 5,899,939) in view of Chou (US 2004/0191292).

Regarding **Claims 1, 9, 17, and 22**, Boyce teaches **a bone-powder-impregnated, porous structure comprising a porous matrix** (column 4, lines 53-56) **made of a biocompatible material** (demineralized bone, column 3, line 11-40) **impregnated with fine bone powder** (column 4, lines 57-61 and column 4, lines 63-65 with bone powder found in column 5, lines 15-16) **obtained by pulverizing living bones and/or teeth** (demineralized bone, column 5, lines 15-16).

Note: It is the Examiner's position that the process of demineralization results in a similar structured bone powder as results from the process of pulverizing. Further, the Examiner notes that the Applicant provides both pulverizing and demineralization as alternative process to produce bone powder, but does not distinguish between any specific characteristics of these methods in the disclosed Specification.

Boyce discloses the invention substantially as claimed but fails to teach that **the fine bone powder comprises sub-micron particles**.

Chou teaches the use of sub-micron particles impregnated within a polymer matrix for a bone scaffold ([0024]). The average diameter of these particles must be 50 microns or less.

Boyce and Chou are concerned with the same field of endeavor, namely porous bone matrices.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the bone powder size of Boyce to have a sub-micron size as taught by Chou in order to embed the particles evenly within the matrix.

Note: It is the Examiner's position that a surface-roughened structure is a porous structure as the process of surface-roughening is one way to produce a porous surface.

Regarding Claims **10, 14, and 25**, Boyce teaches an implant where the entire structure is porous (made of layers of porous material, e.g. column 6, lines 1-6). Further Boyce teaches the porous structure makes a femur, which is a limb (column 6, lines 8-13).

12. Claims 1-2, 5-6, and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith, et al (Smith) (2004/0253279 A1) in view of Boyce, et al (Boyce) (US 5,899,939) and further in view of Chou (US 2004/0191292).

Smith teaches **an impregnated, porous structure comprising a porous matrix** (porous article, [0017]) **made of a biocompatible material** (ceramic, [0043]; hydroxyapatite, [0044]).

Smith discloses the invention substantially as claimed but fails to teach the porous structure **impregnated with fine bone powder obtained by pulverizing living bones and/or teeth**.

Note: The Examiner's positions on demineralization versus pulverization and on surface-roughened structure are discussed supra.

Boyce teaches a porous bone scaffold **impregnated with fine bone powder** (column 4, lines 57-61 and column 4, lines 63-65 with bone powder found in column 5, lines 15-16) **obtained by pulverizing living bones and/or teeth** (demineralized bone, column 5, lines 15-16).

Boyce and Smith are concerned with the same field of endeavor, namely bone matrices.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the impregnating powder of Smith by incorporating the demineralized bone of Boyce in order to promote and/or accelerate new bone growth.

The combination of Smith and Boyce discloses the invention substantially as claimed but fails to teach that **the fine bone powder comprises sub-micron particles**.

Chou teaches the use of sub-micron particles impregnated within a polymer matrix for a bone scaffold ([0024]).

Chou and the combination of Smith and Boyce are concerned with the same field of endeavor, namely porous bone matrices.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the bone powder size of the combination of Smith and Boyce to have a sub-micron size as taught by Chou in order to embed the particles evenly within the matrix.

Regarding **Claims 2 and 18**, Smith teaches pore (or recess) sizes from 15-50 microns ([0043]). Further, Smith teaches at least 1 pore per area of 50 microns x 50 microns discussed as follows. Smith teaches a porosity of 20-95% ([0023]) and a uniform distribution of pores ([0047]). For example, at a porosity of 95% and a pore size of 15 microns, pores cover 95% of the surface area (or 0.95*(50x50) = 2375 microns squared). Each pore (being approximately spherical with a circular cross section, e.g. Figure 2) would have a surface area of (pi*7.5*7.5 = 177 microns squared) meaning that there are approximately 13 pores per area of 50 microns x 50 microns.

Regarding **Claims 5-6 and 19**, Smith teaches a porous matrix made of a ceramic ([0043]) and more specifically the calcium phosphate hydroxyapatite ([0044]).

13. **Claim 26** is rejected under 35 U.S.C. 103(a) as being unpatentable over Boyce, et al (Boyce) (US 5,899,939) in view of Chou (US 2004/0191292) as discussed supra and further in view of Takagi, et al (Takagi) (US 4,654,314).

Although Boyce teaches that Bone-derived implants of any desirable size and/or configuration can be provided (column 4, lines 45-46), Boyce fails to teach specifically a dental root.

The combination of Boyce and Chou discloses the invention substantially as claimed but fails to teach porous structure to be used as a dental root.

Takagi teaches a porous ceramic material used to as a material for a dental root (abstract).

Takagi and the combination of Boyce and Chou are concerned with the same field of endeavor, namely porous bone matrices.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the final product of the combination of Boyce and Chou to take the form of a dental root as taught by Takagi in order to provide replacement prosthesis.

14. **Claims 27 and 28** are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyce, et al (Boyce) (US 5,899,939) in view of Chou (US 2004/0191292) as discussed supra and further in view of Levine, et al (Levine) (US 2003/0220696 A1).

The combination of Boyce and Chou discloses the invention substantially as claimed but fails to teach an autologous bone powder source.

Levine teaches a bone scaffold where the tissues used are autologous ([0024]).

Levine and the combination of Boyce and Chou are concerned with the same field of endeavor, namely porous bone matrices.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the source tissue of the combination of Boyce and Chou by incorporating an autologous tissue source as taught by Levine in order to produce a graft made from the recipient's own cells.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LESLIE COBURN whose telephone number is (571)270-7044. The examiner can normally be reached on M-Th 8:30 AM - 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, please contact the examiner's supervisor, David Isabella, at 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

If there are any inquiries that are not being addressed by first contacting the Examiner or the Supervisor, you may send an email inquiry to TC3700_Workgroup_D_Inquiries@uspto.gov.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/L. C./
Examiner, Art Unit 3774
10/12/2011

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